DEC - 5 2000

K003291

Bayer Diagnostics

ACS:180 and ADVIA Centaur anti-TPO Immunoassays

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	William J. Pignato
Address:	Bayer Diagnostics Corporation 63 North Street Medfield, MA 02052
	Phone: (508) 359-3825 FAX: (508) 359-3356 e-mail: william.pignato.b@bayer.com
Date Summary Prepared:	October 13, 2000

2. Device Information

Proprietary Name:	ADVIA Centaur and ACS: 180 anti-TPO Immunoassay
Common Name:	anti-TPO Immunoassay
Classification Name:	Thyroid autoantibody immunological test system
Class:	Class II
CFR:	21 CFR 866.5870
Product Code:	JZO

3. Predicate Device Information

Name:	DYNOTest® anti-TPO_n
Manufacturer:	BRAHMS Diagnostica, GmbH Neuendorfstrasse 25 D-16761 Hennigsdorf Germany
510(k) Number:	K992791

4. Device Description

The ACS:180 anti-TPO is a competitive chemiluminescence immunoassay intended for the quantitative determination of autoantibodies against thyroid peroxidase in human serum and

plasma. A mouse monoclonal antibody against thyroid peroxidase bound to the solid phase competes with autoimmune anti-thyroid peroxidase antibodies in patient samples, standards, and controls for indirectly labeled native human thyroid peroxidase in the lite reagent. The indirect label consists of a chemiluminescent labeled (acridinium ester) monoclonal antibody against a separate epitope on the added thyroid peroxidase. Following incubation, unreacted labeled thyroid peroxidase and unreacted antibodies from the sample are washed from the reaction mixture. The chemiluminescence of the reacted, labeled thyroid peroxidase is measured in a luminometer. The measured chemiluminescence is inversely proportional to the quantity of anti-thyroid peroxidase antibody in the sample.

5. Statement of Intended Use

The ACS:180 and ADVIA Centaur anti-TPO Immunoassays are competitive, chemiluminescence immunoassays for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum or plasma for use on the ACS:180 and ADVIA Centaur automated analyzers marketed by Bayer Corporation. The anti-TPO Immunoassay is used as an aid in the diagnosis of Hashimoto's and Graves' disease, autoimmune diseases affecting the thyroid gland.

6. Summary of Technological Characteristics

The ACS:180 and ADVIA Centaur anti-TPO Immunoassays are similar to the BRAHMS Diagnostica DYNOTest® anti-TPO kit (K992791) in the indications for use, format, solid phase, performance characteristics, and results. The ACS:180 and ADVIA Centaur anti-TPO tests differ mainly in their intended use on an automated analyzer as compared to a manual coated tube technique. In the automated method, a chemiluminogenic molecule (acridinium ester) is used to replace the ^{125}I signal used in the DYNOtest anti-TPO manual assay.

7. Method Comparison

Equivalence to Predicate Device

Substantial equivalence to the DYNOTest kit, cleared under K992791, is based on clinical comparison using 530 serum samples from normal blood donors (n=253) and patients with Graves' disease and Hashimoto's thyroiditis (n=277). Overall agreement of both groups based on a 2 X 2 agreement table was 528/530 = 99.6%.

Normal patients:

		DYNOTest anti-TPO	
		Positive	Negative
ACS:180	Positive	28	0
	Negative	0	225

% Agreement = 100.0

Graves patients:

		DYNOTest anti-TPO	
		Positive	Negative
ACS:180	Positive	64	1
	Negative	0	29

% Agreement = 98.9

Hashimoto's patients:

		DYNOTest anti-TPO	
		Positive	Negative
ACS:180	Positive	173	1
	Negative	0	9

% Agreement = 99.5

Overall Agreement: 528/530 = 99.6 %

This correlation study demonstrates that the ACS:180 anti-TPO assay is substantially equivalent to the legally marketed predicate device, the BRAHMS Diagnostica DYNOTest anti-TPO assay.

ADVIA Centaur

For 149 serum samples in the range of 0 to 3000 U/mL, the relationship between the ADVIA Centaur anti-TPO assay and the ACS:180 anti-TPO assay is described by the equation:

ADVIA Centaur anti-TPO = 1.05 (ACS:180 anti-TPO) – 15.1 U/mL
Correlation coefficient (r) = 0.981

The diagnostic concordance between the two assays is shown in the following table:

Category	**ACS:180 Positive**	**ACS:180 Negative**
ADVIA Centaur Positive	75	4
ADVIA Centaur Negative	0	70

Agreement: 145 / 149 = 97.3 %

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 5 2000

Mr. William J. Pignato
Director of Regulatory Affairs
Bayer Corporation
63 North Street
Medfield, Massachusetts 02052-1688

Re: K003291
Trade Name: Bayer Diagnostics ACS: 180 and ADVIA: Centaur Anti-TPO Assay
Regulatory Class: II
Product Code: JZO
Dated: October 13, 2000
Received: October 20, 2000

Dear Mr. Pignato:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003291

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur anti-TPO Assay

Indications for Use:

The ACS:180 and ADVIA Centaur anti-TPO Immunoassays are competitive, chemiluminescence immunoassays for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum or plasma for use on the ACS:180 and ADVIA Centaur automated analyzers marketed by Bayer Corporation. The anti-TPO Immunoassay is used as an aid in the diagnosis of Hashimoto's and Graves' disease, autoimmune diseases affecting the thyroid gland.

Louis E. Mayfield for Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003291

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**